# Amendment No. 1 to HB3940

# Harwell Signature of Sponsor

AMEND Senate Bill No. 3806\*

House Bill No. 3940

by deleting all language after the enacting clause and by substituting instead the following:

SECTION 1. Tennessee Code Annotated title 56, is amended by adding SECTION 2 through SECTION 26 as a newly designated chapter thereto.

SECTION 2. This chapter shall be known and may be cited as the "Tennessee Health Carrier Grievance and External Review Procedure Act." The purpose of this chapter is to provide standards for the establishment and maintenance of procedures by health carriers to assure that covered persons and health care providers have the opportunity for the appropriate resolution of grievances, as defined in this chapter.

SECTION 3. For purposes of this chapter, unless the context otherwise requires:

- (1) "Adverse determination" means:
- (A) A determination by a health carrier or its designee utilization review organization that, based upon the information provided, a request for a benefit under the health carrier's health benefit plan does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness and the requested benefit is therefore denied, reduced or terminated or payment is not provided or made, in whole or in part, for the benefit;
- (B) The denial, reduction, termination or failure to provide or make payment, in whole or in part, for a benefit based on a determination by a health carrier of a covered person's eligibility to participate in the health carrier's health benefit plan; or

- (C) Any prospective review or retrospective review determination that denies, reduces, or terminates or fails to provide or make payment for, in whole or in part, a benefit;
- (2) "Aggrieved person" means:
  - (A) A health care provider;
  - (B) A covered person; or
  - (C) A covered person's authorized representative.
- (3) "Authorized representative" means:
- (A) A person to whom a covered person has given express written consent to represent the covered person for purposes of this chapter;
- (B) A person authorized by law to provide substituted consent for a covered person;
- (C) A family member of the covered person or the covered person's treating health care professional when the covered person is unable to provide consent;
- (D) A health care professional when the covered person's health benefit plan requires that a request for a benefit under the plan be initiated by the health care professional; or
- (E) In the case of an urgent care request, a health care professional with knowledge of the covered person's medical condition;
- (4) "Clinical peer" means a physician or other health care professional who holds a non-restricted license in a state of the United States and in the same or similar specialty that would typically manage the medical condition, procedure or treatment under review;
- (5) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and practice guidelines used by the health

carrier to determine the medical necessity and appropriateness of health care services;

- (6) "Closed plan" means a managed care plan that requires covered persons to use participating providers under the terms of the managed care plan or the plan will not provide covered benefits to the covered person;
- (7) "Commissioner" means the commissioner of commerce and insurance;
- (8) "Covered benefits" or "benefits" means those health care services to which a covered person is entitled under the terms of a health benefit plan;
- (9) "Covered person" means a policyholder, subscriber, enrollee or other individual participating in a health benefit plan;
- (10) "Emergency medical condition" means the sudden and, at the time, unexpected onset of a health condition that requires immediate medical attention, where failure to provide medical attention would result in serious impairment to bodily functions, serious dysfunction of a bodily organ or part, or would place the person's health in serious jeopardy;
- (11) "Emergency services" means health care items and services furnished or required to evaluate and treat an emergency medical condition;
- (12) "External review organization" means an entity that conducts independent external reviews of adverse determinations and final adverse determinations of a health carrier:
- (13) "Facility" means an institution licensed under title 68 providing health care services or a health care setting, including but not limited to, hospitals and other licensed inpatient centers, ambulatory surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory and imaging centers, and rehabilitation;
- (14) "Final adverse determination" means an adverse determination involving a covered benefit that has been upheld by a health carrier at the

completion of the health carrier's internal grievance process procedures as set forth in this chapter.

- (15) "Grievance" means a written appeal of an adverse determination or final adverse determination submitted by or on behalf of a covered person regarding:
  - (A) Availability, delivery or quality of health care services regarding an adverse determination;
  - (B) Claims payment, handling or reimbursement for health care services:
  - (C) Matters pertaining to the contractual relationship between a covered person and a health carrier; or
  - (D) Matters pertaining to the contractual relationship between a health care provider and a health carrier;
- (16) "Health benefit plan" means a policy, contract, certificate or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services;
- (17) "Health care professional" means a physician or other health care practitioner licensed, accredited or certified to perform specified health care services consistent with state law;
- (18) "Health care provider" or "provider" means a health care professional or a facility;
- (19) "Health care services" means services for the diagnosis, prevention, treatment, cure or relief of a health condition, illness, injury or disease;
- (20) "Health carrier" means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, that contracts or offers to contract to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a nonprofit

hospital and health service corporation, or any other entity providing a plan of health insurance, health benefits or health care services;

- (21) "Managed care plan" means a health benefit plan that requires a covered person to use, or creates incentives, including financial incentives, for a covered person to use health care providers managed, owned, under contract with or employed by the health carrier. "Managed care plan" includes:
  - (A) A closed plan, as defined in subdivision (6); and
  - (B) An open plan, as defined in subdivision (26);
- (22) "Medical or scientific evidence" means evidence found in the following sources, provided that subdivisions (A) through (B) shall be considered to have more evidentiary value than subdivision (E) and subdivision (E), when considered solely and in the absence of subdivisions (A) through (B), shall not be sufficient to establish medical or scientific evidence for purposes of this chapter:
  - (A) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;
  - (B) Peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's Library of Medicine for indexing in Index Medicus (Medline) and Elsevier Science Ltd. for indexing in Excerpta Medicus (EMBASE);
  - (C) Medical journals recognized by the secretary of health and human services under § 1861(t)(2) of the federal Social Security Act, codified in 42 USC § chapter 7.
    - (D) The following standard reference compendia:

- (i) The American Hospital Formulary Service–Drug Information;
  - (ii) Drug Facts and Comparisons;
- (iii) The American Dental Association Accepted Dental Therapeutics;
  - (iv) The United States Pharmacopoeia–Drug Information;
- (E) Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including:

or

- (i) The Federal Agency for Healthcare Research and Quality;
  - (ii) The National Institutes of Health;
  - (iii) The National Cancer Institute;
  - (iv) The National Academy of Sciences;
  - (v) The Centers for Medicare & Medicaid Services;
  - (vi) The Federal Food and Drug Administration; and
- (vii) Any national board recognized by the NationalInstitutes of Health for the purpose of evaluating the medical value of health care services;
- (23) "Medically necessary" or "medical necessity" means health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
  - (A) In accordance with generally accepted standards of medical practice;

- (B) Clinically appropriate, in terms of type, frequency, extent, site and duration; and considered effective for the patient's illness, injury or disease; and
- (C) Not primarily for the convenience of the patient, physician, or other health care provider; and
- (D) Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease:
- (24) "NAIC" means the National Association of Insurance Commissioners;
- (25) "Network" means the group of participating providers providing services to a managed care plan;
- (26) "Open plan" means a managed care plan, other than a closed plan, that provides incentives, including financial incentives, for covered persons to use participating providers under the terms of the managed care plan;
- (27) "Participating provider" means a provider who, under a contract with the health carrier or with its contractor or subcontractor, has agreed to provide health care services to covered persons with an expectation of receiving payment, other than coinsurance, copayments or deductibles, directly or indirectly from the health carrier;
- (28) "Person" means an individual, a corporation, a partnership, an association, a joint venture, a joint stock company, a trust, an unincorporated organization, any similar entity or any combination of the entities listed in this subdivision (28);
- (29) "Prospective review" means utilization review conducted prior to an admission or the provision of a health care service or a course of treatment in accordance with a health carrier's requirement that the health care service or

course of treatment, in whole or in part, be approved prior to its provision or admission;

- (30) "Register" means the written records kept by a health carrier to document all grievances received during a calendar year;
- (31) "Retrospective review" means any review of a request for a benefit that is not a prospective review request. Retrospective review does not include the review of a claim that is limited to veracity of documentation or accuracy of coding; and

(32)

- (A) "Urgent care request" means a request for a health care service or course of treatment with respect to which the time periods for making non-urgent care request determination:
  - (i) Could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function; or
  - (ii) In the opinion of a physician with knowledge of the covered person's medical condition, would subject the covered person to severe pain that cannot be adequately managed without the health care service or treatment that is the subject of the request;

(B)

- (i) In determining whether a request is to be treated as an urgent care request, an individual acting on behalf of the health carrier shall apply the judgment of a prudent layperson who possesses an average knowledge of health and medicine.
- (ii) Any request that a physician with knowledge of the covered person's medical condition determines is an urgent care

request within the meaning of subdivision (32)(A) shall be treated as an urgent care request.

# SECTION 4.

- (a) Except as otherwise specified, this chapter shall apply to all health carriers.
  - (b) This chapter shall not apply to a policy or certificate that provides:
  - (1) Coverage only for a specified disease; specified accident or accident-only coverage; credit; dental; disability income; hospital indemnity; long-term care insurance, as defined by § 56-42-103; vision care or any other limited supplemental benefit or to a Medicare supplement policy of insurance as defined by the commissioner;
  - (2) Coverage under a plan through Medicare, Medicaid, or the Federal Employees Health Benefits program (FEHB);
  - (3) Any coverage issued under 10 U.S.C. § 1072 and any coverage issued as supplement to that coverage;
  - (4) Any coverage issued as supplemental to liability insurance; workers' compensation or similar insurance; automobile medical-payment insurance or any insurance under which benefits are payable without regard to fault; whether written on a group blanket or individual basis; or
  - (5) Any plan exempt from regulation under this title due to the Employee Retirement Income Security Act of 1974 (ERISA), compiled in 29 U.S.C. §1144.

SECTION 5. Nothing in this chapter shall limit or restrict the health carrier from denying coverage on the grounds that the services are determined not to be medically necessary.

SECTION 6.

- (a) A health carrier shall maintain written records to document all grievances received during a calendar year. The register shall be maintained in a manner that is reasonably clear and accessible to the commissioner.
- (b) A request for a first level review of a grievance involving an adverse determination shall be processed in compliance with SECTION 8 and is required to be included in the health carrier's register.
- (c) A request for a second level review of a grievance involving an adverse determination that may be conducted pursuant to SECTION 9 shall be included in the health carrier's register.
- (d) For each grievance, the register shall contain, at a minimum, the following information:
  - (1) A general description of the reason for the grievance;
  - (2) The date the grievance was received;
  - (3) The date of each review or, if applicable, review meeting;
  - (4) The resolution at each level of the grievance, if applicable;
  - (5) The date of resolution at each level, if applicable; and
  - (6) The name of the aggrieved person for whom the grievance was filed.

(e)

(1) A health carrier shall retain the register compiled for a calendar year for the shorter of five (5) years or until the commissioner has adopted a final report of an examination that contains a review of the register for such calendar year.

(2)

(A) A health carrier shall submit to the commissioner, at least annually, a report in the format specified by the commissioner.

- (B) The report shall include for each type of health benefit plan offered by the health carrier:
  - (i) The number of covered lives that fall under this chapter's protections;
    - (ii) The total number of grievances;
  - (iii) The number of grievances for which a covered person and health care provider requested a second level voluntary grievance review pursuant to SECTION 9;
  - (iv) The number of grievances resolved at each level, if applicable, and their resolution; and
  - (v) A synopsis of actions being taken to correct problems identified.

#### SECTION 7.

- (a) Except as specified in SECTION 10, a health carrier shall use written procedures for receiving and resolving grievances from aggrieved persons, as provided in SECTIONS 8 and 9, unless otherwise provided by this chapter.
- (b) A health carrier shall file with the commissioner a copy of the procedures required under subsection (a), including all forms used to process requests made pursuant to SECTIONS 8 and 9 of this chapter. Any subsequent material modifications to the documents also shall be filed.
- (c) A description of the grievance procedures required under this section shall be set forth in or attached to the membership booklet, provider manual, and health carrier's web site. The health carrier may include a description of the grievance procedures in the policy, certificate, outline of coverage or other evidence of coverage provided to aggrieved persons.

SECTION 8.

- (a) Within one-hundred and eighty (180) days after the date of receipt of a notice of an adverse determination, an aggrieved person may file a grievance with the health carrier requesting a first level review of the adverse determination.
- (b) The health carrier shall provide the aggrieved person with the name and address of the organizational unit or department designated to coordinate the first level review on behalf of the health carrier.

(c)

(1)

- (A) An aggrieved person does not have the right to attend, or to have a representative in attendance at the first level review; provided, that the aggrieved person is entitled to:
  - (i) Submit written comments, documents, records and other material relating to the request for benefits for the reviewer or reviewers to consider when conducting the review; and
  - (ii) Receive from the health carrier, upon request and free of charge, reasonable access to, and copies of all documents, records and other information relevant to the covered person's request for benefits.
- (B) For purposes of subdivision (c)(1)(A)(ii), a document, record or other information shall be considered relevant to a aggrieved person's request for benefits if the document, record or other information:
  - (i) Was relied upon in making the benefit determination;
  - (ii) Was submitted, considered or generated in the course of making the adverse determination, without regard to whether the document, record or other

information was relied upon in making the benefit determination;

- (iii) Demonstrates that, in making the benefit determination, the health carrier or its designated representatives applied required administrative procedures and safeguards with respect to the covered person as other similarly situated covered persons; or
- (iv) Constitutes a statement of policy or guidance with respect to the health benefit plan concerning the denied health care service or treatment for the covered person's diagnosis, without regard to whether the advice or statement was relied upon in making the benefit determination.
- (2) The health carrier shall make the provisions of subdivision
  (c)(1) known to the aggrieved person within five (5) business days after
  the date of receipt of the grievance; provided, that the request was made
  to the appropriate organizational unit or department designated by the
  health carrier.
- (d) For purposes of calculating the time periods within which a determination is required to be rendered and notice provided under subsection (e), the time period shall begin on the date the grievance requesting the first level review is filed with the health carrier in accordance with the health carrier's procedures established pursuant to SECTION 8, without regard to whether all of the information necessary to make the determination accompanies the filing.

(e)

(1) A health carrier shall notify and issue a decision, in writing or electronically, to the aggrieved person within the time frames provided in subdivisions (e)(2) and (3).

- (2) With respect to a grievance requesting a first level review of an adverse determination involving a prospective review request, the health carrier shall notify and issue a decision within a reasonable period of time that is appropriate given the covered person's medical condition, but no later than thirty (30) days after the date of the health carrier's receipt of the grievance requesting the first level review made pursuant to subsection (a).
- (3) With respect to a grievance requesting a first level review of an adverse determination involving a retrospective review request, the health carrier shall notify and issue a decision within a reasonable period of time, but no later than sixty (60) days after the date of the health carrier's receipt of the grievance requesting the first level review made pursuant to subsection (a).
- (f) The decision issued pursuant to subsection (e) shall set forth, in a manner calculated to be understood by the aggrieved person:
  - (1) The titles and qualifying credentials of the person or persons participating and reviewing in the first level review;
  - (2) A statement of each reviewer's understanding of the grievance;
  - (3) Each reviewer's decision in clear terms and the contract basis or medical rationale in sufficient detail for the aggrieved person to respond further to the health carrier's position;
  - (4) A reference to the evidence or documentation used as the basis for the decision;
  - (5) For a first level review decision issued pursuant to subsection(e) involving an adverse determination:
    - (A) The specific reason or reasons for the adverse determination:

- (B) A reference to the specific plan provisions on which the determination is based;
- (C) A statement that the aggrieved person is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records and other information relevant, as the term "relevant" is defined in subdivision (c)(1)(B), to the covered person's benefit request;
- (D) If the health carrier relied upon an internal rule, guideline, protocol or other similar criterion to make the adverse determination, either the specific rule, guideline, protocol or other similar criterion or a statement that a specific rule, guideline, protocol or other similar criterion was relied upon to make the adverse determination and that a copy of the rule, guideline, protocol or other similar criterion will be provided free of charge to the aggrieved person upon request and the date such policy was effective;
- (E) If the adverse determination is based on medical necessity, either an explanation of the criteria for making the determination, applying the terms of the health benefit plan to the covered person's medical circumstances, or a statement that an explanation will be provided to the aggrieved person, free of charge upon request; and
  - (F) If applicable, instructions for requesting:
  - (i) A copy of the rule, guideline, protocol or other similar criterion relied upon in making the adverse determination, as provided in subdivision (f)(5)(D); and
  - (ii) The written statement of the criteria for the determination, as provided in subdivision (f)(5)(E);

- (6) If applicable, a statement indicating:
- (A) A description of the process to obtain a second level review of the first level review's decision involving an adverse determination, if the aggrieved person, wishes to request a second level review pursuant to SECTION 9;
- (B) The written procedures governing the second level review, including any required time frame for the review; and
- (C) A description of the procedures for obtaining an external review of the adverse determination pursuant to this chapter if the aggrieved person, decides not to file for a second review of the first level review's decision involving an adverse determination.

## SECTION 9.

(a) A health carrier shall establish a second level review process to give aggrieved persons, who are dissatisfied with the first level review decision, the option of requesting a second level review.

(b)

- (1) Health carriers required by this section to establish a second level review process shall provide aggrieved persons with notice pursuant to SECTION 8, as appropriate, of the option to file a request with the health carrier for a second level review of the first level review's decision rendered pursuant to SECTION 8.
- (2) Upon receipt of a request for a second level review, the health carrier shall send notice within five (5) business days to the covered person or, if applicable, the covered person's authorized representative of the covered person's right to:

- (A) Request, within the time frame specified in subdivision(b)(3)(A), the opportunity to appear in person before a reviewpanel of the health carrier's designated representatives;
- (B) Receive from the health carrier, upon request, copies of all documents, records and other information that is not confidential or privileged relevant to the covered person's request for benefits;
- (C) Present the covered person's case to the review panel;
- (D) Submit written comments, documents, records and other material relating to the request for benefits to the review panel for consideration when conducting the second level review both before and, if applicable, during the second level review.
- (E) If applicable, ask questions of any representative of the health carrier on the review panel; provided, such questions are governed and relevant to the subject matter of the second level review; and
- (F) Be assisted or represented by an individual of the covered person's choice, at the expense of such covered person.(3)
- (A) A covered person or covered person's authorized representative wishing to request to appear in person before the review panel of the health carrier's designated representatives shall make the request to the health carrier within ten (10) business days after the date of receipt of the notice sent in accordance with subdivision (b)(2).
- (B) The covered person's right to a fair review shall not be made conditional on the covered person or the covered person's

authorized representative's appearance at the second level review.

- (4) Upon receipt of a request for a second level review, the health carrier shall send notice within five (5) business days to the health care provider of the health care provider's right to:
  - (A) Receive from the health carrier, upon request, copies of all documents, records and other information that is not confidential or privileged relevant to the aggrieved person's request for benefits;
  - (B) Submit written comments, documents, records and other material relating to the request for benefits for the review panel to consider when conducting the second level review; and
  - (C) If applicable, ask questions of any representative of the health carrier on the review panel; provided, such questions are governed and relevant to the subject matter of the second level review.

(c)

(1)

- (A) With respect to a second level review of a first level review decision rendered pursuant to SECTION 8, a health carrier shall appoint a review panel to review the request.
- (B) In conducting the review, the review panel shall take into consideration all comments, documents, records and other information regarding the request for benefits submitted by the aggrieved person pursuant to subdivision (b)(2), without regard to whether the information was submitted or considered in reaching the first level review's decision.

(C) The review panel shall have the legal authority to bind the health carrier to the review panel's decision.

(2)

- (A) Except as provided in subdivision (c)(2)(B), a majority of the review panel shall be comprised of individuals who were not involved in the first level review decision rendered pursuant to SECTION 8.
- (B) An individual who was involved with the first level review decision may be a member of the review panel or appear before the review panel to present information or answer questions.
- (C) The health carrier shall ensure that the individuals conducting the second level review of the first level review decision have appropriate expertise or have access to appropriate expertise that consists of similar knowledge and training or specialty that typically is involved in managing the medical condition, procedure or treatment that is the subject of the grievance under second level review.
- (D) No member of the review panel shall have a direct financial interest in the outcome of the second level review.
- (d) The procedures for conducting the second level review shall include the provisions described in subdivisions (1) through (5):
  - (1) The review panel shall schedule and hold the second level review within sixty (60) business days after the date of receipt of the request for a second level review.
    - (A) The aggrieved person shall be notified in writing at least fifteen (15) business days in advance of the date of the second level review.

- (B) The health carrier shall not unreasonably deny a request for postponement of the second level review made by the aggrieved person.
- (2) The second level review shall be held during regular business hours at a location that meets the guidelines established by the Americans with Disabilities Act, compiled in 42 U.S.C. § 1201 et seq, to the aggrieved person;
- (3) In cases where an in-person second level review is not practical for geographic reasons, or any other reason, a health carrier shall offer the aggrieved person, the opportunity to communicate with the review panel, at the health carrier's sole expense, by conference call or other appropriate technology as determined by the health carrier;
- (4) The review panel shall provide the aggrieved person notice of the right to have an attorney present at the second level review; and
- (5) The review panel shall issue a written or electronic decision, as provided in subsection (e), to the aggrieved person within five (5) business days of completing the second level review meeting.
- (e) A decision issued pursuant to this section shall include the:
- (1) Titles and qualifying credentials of the reviewers on the review panel;
- (2) Statement of the review panel's understanding of the nature of the grievance and all pertinent facts;
  - (3) Rationale for the review panel's decision;
- (4) Reference to evidence or documentation considered by the review panel in rendering its decision; and
- (5) In cases concerning a grievance involving an adverse determination:

- (A) Instructions for requesting a written statement of the clinical rationale, including the clinical review criteria used to make the determination; and
- (B) If applicable, a statement describing the procedures for obtaining an external review of the adverse determination pursuant to this chapter.

#### SECTION 10.

- (a) A health carrier shall establish written procedures for the expedited review of urgent care requests of grievances involving an adverse determination.
- (b) In addition to subsection (a), a health carrier shall provide expedited review of a grievance involving an adverse determination with respect to concurrent review of urgent care requests involving an admission, availability of care, continued stay or health care service for a covered person who has received emergency services, but has not been discharged from a facility.
- (c) The procedures shall allow an aggrieved person to request an expedited review under this section orally, in writing or electronically.
- (d) A health carrier shall appoint an appropriate clinical peer, or peers as would typically manage the case being reviewed, to review the adverse determination. The clinical peer or peers shall not have been involved in rendering the initial adverse determination.
- (e) In an expedited review, the health carrier shall provide or transmit all necessary documents and information considered when making the adverse determination to the aggrieved person participating in the expedited review process electronically or by telephone, facsimile or any other expeditious method available.

(f)

(1) An expedited review decision shall be rendered and the aggrieved person shall be notified of the decision in accordance with

subsection (h) as expeditiously as the covered person's medical condition requires, but in no event more than seventy-two (72) hours after the receipt of the request for the expedited review.

- (2) If the expedited review is of a grievance involving an adverse determination with respect to a concurrent review of an urgent care request, the service shall be continued until the covered person or covered person's authorized representative has been notified of the determination or until the health care provider determines that the urgent care is no longer appropriate or necessary.
- (g) For purposes of calculating the time periods within which a decision is required to be rendered under subsection (f), the time period within which the decision is required to be rendered shall begin on the date that the request is filed with the health carrier in accordance with the health carrier's procedures established pursuant to SECTION 8; without regard to whether all the information necessary to make the determination accompanies the filing.

(h)

- (1) A notification of a decision under this section shall, in a manner calculated to be understood by the aggrieved person, set forth:
  - (A) The titles and qualifying credentials of the person or persons participating in the expedited review process;
  - (B) A statement of the reviewers' understanding of the grievance;
  - (C) The reviewers' decision in clear terms and the contract basis or medical rationale in sufficient detail for the aggrieved person to respond further to the health carrier's position;
  - (D) A reference to the evidence or documentation used as the basis for the decision; and

- (E) If the decision involves an adverse determination, the notice shall provide:
  - (i) The specific reason or reasons for the adverse determination;
  - (ii) Reference to the specific plan provisions on which the determination is based;
  - (iii) A description of any additional material or information necessary for the covered person to complete the request, including an explanation of why the material or information is necessary to complete the request;
  - (iv) If the health carrier relied upon an internal rule, guideline, protocol or other similar criterion, effective at the time of service, to make the adverse determination, either the specific rule, guideline, protocol or other similar criterion or a statement that a specific rule, guideline, protocol or other similar criterion was relied upon to make the adverse determination and a copy of the rule, guideline, protocol or other similar criterion will be provided free of charge to the aggrieved person upon request;
  - (v) If the adverse determination is based on medical necessity, an explanation of the criteria for making the determination, applying the terms of the health benefit plan to the covered person's medical circumstances or a statement that an explanation will be provided to the aggrieved person free of charge upon request;
    - (vi) If applicable, instructions for requesting:
    - (a) A copy of the rule, guideline, protocol or other similar criterion relied upon in making the

adverse determination in accordance with subdivision (h)(1)(E)(iv); or

- (b) The written statement of the criteria for the adverse determination in accordance with subdivision (h)(1)(E)(v); and
- (vii) A statement describing the procedures for obtaining an external review of the adverse determination pursuant to this chapter.

(2)

- (A) A health carrier may provide the notice required under this section orally, in writing or electronically.
- (B) If notice of the adverse determination is provided orally, the health carrier shall provide written or electronic notice of the adverse determination within three (3) days following such oral notification.

SECTION 11. The commissioner may, after notice and hearing, promulgate reasonable rules and regulations to carry out the provisions of this chapter. Such rules and regulations shall be subject to review in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 12. A person that violates this chapter shall be subject to the penalties set forth in § 56-2-305.

# SECTION 13.

- (a) For purposes of this section, "approved entity" means:
  - (1) URAC, or
- (2) Other nationally recognized private accrediting entity employing standards for the accreditation of external review programs that the commissioner deems are substantially equivalent to the

standards for conducting an external review pursuant to SECTIONS 14 through 19 of this chapter.

- (b) A health carrier may elect, in writing to the commissioner, to conduct its external review program in accordance with:
  - (1) SECTIONS 14 through 19 of this chapter, or
  - (2) The external review program of an approved entity, provided that the health carrier receives and maintains accreditation from the approved entity. SECTIONS 21 and 22 of this chapter shall not apply to a health carrier that receives and maintains accreditation from the approved entity.
- (c) The commissioner may evaluate the external review procedures of an approved entity. If after a hearing is conducted in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, part 3, the commissioner finds that an approved entity has amended its external review procedures to the extent that such procedures are no longer consistent with the purposes of this chapter, the commissioner shall issue a written order specifying in what respects those procedures are inconsistent.
- (d) A health carrier that has elected to conduct its external review program in accordance with the standards of an approved entity, that is the subject of the commissioner's order issued pursuant to subsection (c), shall have sixty (60) days from the effective date of the commissioner's order to:
  - (1) Elect, in writing, to utilize another external review program under subsection (b); or
  - (2) Demonstrate to the commissioner's satisfaction that the approved entity has subsequently amended its procedures so that such procedures are consistent with the purposes of this chapter.

SECTION 14.

(a) A health carrier shall notify the aggrieved person in writing of the right to request an external review to be conducted pursuant to SECTIONS 17 and 19 of this chapter and include the appropriate statements and information set forth in subsection (b) of this section at the same time that the health carrier sends written notice of a final adverse determination. As part of the written notice required under this subsection (a), a health carrier shall include the following, or substantially equivalent language:

We have denied your request for the provision of or payment for a health care service or course of treatment. You have the right to have our decision reviewed by health care professionals who have no association with us if our decision involved making a judgment as to the medical necessity, appropriateness, health care setting, level of care or effectiveness of the health care service or treatment you requested by submitting a written request for external review to us.

- (b) The health carrier shall include the following in the notice required under subsection (a):
  - (1) For a notice related to an adverse determination, a statement informing the aggrieved person that:
    - (A) If the covered person has a medical condition where the timeframe for completion of an expedited review of a grievance involving an adverse determination set forth in SECTION 10 would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function, the aggrieved person may file a request for an expedited external review to be conducted pursuant to SECTION 18.
    - (B) The aggrieved person may file a grievance under the health carrier's internal grievance process as set forth in

SECTION 8. An aggrieved person shall be considered to have exhausted the health carrier's internal grievance process for purposes of this section, if the aggrieved person:

- (i) Has filed a grievance involving an adverse determination pursuant to SECTION 8; and
- (ii) Has not received a written decision on the grievance from the health carrier within thirty (30) days for prospective review determinations and sixty (60) days for retrospective review determinations following the date the aggrieved person filed the grievance with the health carrier unless the aggrieved person requested or agreed to a delay.
- (2) For a notice related to a final adverse determination, a statement informing the aggrieved person that:
  - (A) If the covered person has a medical condition where the timeframe for completion of a standard external review pursuant to SECTION 17 or SECTION 19 would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function, the aggrieved person may file a request for an expedited external review pursuant to SECTION 18 or SECTION 19(n).
  - (B) If the final adverse determination concerns an admission, availability of care, continued stay or health care service for which the covered person received emergency services, but has not been discharged from a facility, the aggrieved person may file a request for an expedited external review pursuant to SECTION 18 or SECTION 19(n).

- (c) In addition to the information to be provided pursuant to subdivision (b)(1), the health carrier shall include a copy of the description of both the standard and expedited external review procedures highlighting the provisions in the external review procedures that give the aggrieved person the opportunity to submit additional information and any forms used to process an external review.
- (d) As part of any forms provided under subdivision (b)(2), the health carrier shall include an authorization form that complies with the requirements of 45 CFR § 164.508, by which the covered person, for purposes of conducting an external review under this chapter, authorizes the health carrier and the covered person's treating health care provider to disclose protected health information, including but not limited to, medical records, concerning the covered person that are pertinent to the external review.

## SECTION 15.

- (a) Except for a request for an expedited external review as set forth in SECTION 18 or 19(n), all requests for external review shall be made in writing to the health carrier.
- (b) Unless otherwise set forth by this chapter, an aggrieved person may file a request for external review after the receipt of a final adverse determination. SECTION 16.
- (a) Except as provided in subsection (b), a request for an external review pursuant to SECTION 17 or SECTION 19 shall not be made until the aggrieved person has exhausted the health carrier's internal grievance process as set forth in this chapter.
  - (1) An aggrieved person shall be considered to have exhausted the health carrier's internal grievance process for purposes of this section, if the aggrieved person:
    - (A) Has filed a grievance involving an adverse determination pursuant to SECTION 8; and

- (B) Has not received a written decision on the grievance from the health carrier within thirty (30) days for prospective review determinations and sixty (60) days for retrospective review determinations following the date that the aggrieved person filed the grievance with the health carrier unless the aggrieved person requested or agreed to a delay.
- (2) Notwithstanding subdivision (a)(1)(B), an aggrieved person, may not file a request for an external review of an adverse determination involving a retrospective review determination until the covered person has exhausted the health carrier's internal grievance process.
- (b) A request for an external review of an adverse determination may be filed before the covered person has exhausted the heath carrier's internal grievance procedures, as set forth in SECTION 8, whenever the health carrier agrees to waive the exhaustion requirement.
- (c) If the requirement to exhaust the health carrier's internal grievance procedures is waived pursuant to subsection (b), the aggrieved person may file a request in writing for a standard external review as set forth in SECTION 17 or SECTION 19.

#### SECTION 17.

- (a) Within six (6) months after the date of receipt of a notice of an adverse determination or final adverse determination pursuant to SECTION 14, an aggrieved person may file a request for an external review with the health carrier.
- (b) Within ten (10) business days following the date of receipt of the copy of the external review request, the health carrier shall complete a preliminary review of the request to determine whether:
  - (1) The individual is or was a covered person in the health benefit plan at the time that the health care service was requested or, in the case

of a retrospective review, was a covered person in the health benefit plan at the time that the health care service was provided;

- (2) The health care service that is the subject of the adverse determination or the final adverse determination is a covered service under the covered person's health benefit plan;
- (3) The covered person has exhausted the health carrier's internal grievance process as set forth in this chapter unless the covered person is not required to exhaust the health carrier's internal grievance process pursuant to SECTION 16; and
- (4) The covered person has provided all the information and forms required to process an external review, including the release form provided pursuant to SECTION 14.
- (c) Within three (3) business days after completion of the preliminary review, the health carrier shall notify the aggrieved person in writing whether:
  - (1) The request is complete; and
  - (2) The request is eligible for external review.
  - (d) If the request set out in subsection (a):
  - (1) Is not complete, the health carrier shall notify the aggrieved person in writing and include in the notice what information or materials are needed to make the request complete; or
  - (2) Is not eligible for external review, the health carrier shall notify the aggrieved person in writing and include in the notice the reasons for its ineligibility.
- (e) The notice of initial determination shall include a statement informing the aggrieved person that a health carrier's initial determination that the external review request is ineligible for review may be appealed to the commissioner.

- (f) The commissioner may determine that a request is eligible for external review under this chapter notwithstanding a health carrier's initial determination that the request is ineligible and require that it be referred for external review.
  - (1) In making a determination under this subdivision (f), the commissioner's decision shall be made in accordance with the terms of the covered person's health benefit plan and shall be subject to all applicable provisions of this chapter.
  - (2) Whenever the health carrier or commissioner determines that a request is eligible for external review following the preliminary review conducted pursuant to subdivision (c)(2), within three (3) business days after the determination by the health carrier or within three (3) business days after the date of receipt of the determination by the commissioner, the health carrier shall notify the aggrieved person in writing of the request's eligibility and acceptance for external review.
- (g) The health carrier shall include in the notice provided to the aggrieved person, a statement that additional information may be submitted in writing to the health carrier within six (6) business days following the date of receipt of the notice provided pursuant to subdivision (f)(2), and that the external review organization shall consider such additional information when conducting the external review. The health carrier is not required to, but may, accept and forward to the external review organization for consideration such additional information submitted by the aggrieved person after six (6) business days.
- (h) Within six (6) business days after the date of receipt of the notice provided pursuant to subsection (g), the health carrier shall provide to the external review organization any documents and information considered in making the adverse determination or final adverse determination.

- (1) Failure by the health carrier to provide the documents and information within the time specified in subsection (h) shall not delay the external review.
- (2) If the health carrier fails to provide the documents and information within the time specified in subsection (h), the external review organization may terminate the external review and make a decision to reverse the adverse determination or final adverse determination.
- (3) The external review organization shall notify the health carrier within one (1) business day of its decision to reverse the adverse determination or final adverse determination pursuant to subdivision (h)(2). The health carrier shall notify the aggrieved person within three (3) business days of the external review organization's decision.
- (i) The external review organization shall review all of the information and documents received pursuant to subsection (g) and any other information submitted in writing by the aggrieved person.
- (j) Upon receipt of the information required to be forwarded pursuant to subsection (g), the health carrier may reconsider its final adverse determination that is the subject of the external review.
  - (1) Reconsideration by the health carrier of its final adverse determination shall not delay or terminate the external review.
  - (2) The external review may only be terminated by the health carrier if the health carrier decides, upon completion of its reconsideration, to reverse its final adverse determination and provide coverage or payment for the health care service that is the subject of the adverse determination or final adverse determination. If the health carrier reverses its previous determinations pursuant to this subsection (j), the health carrier shall not at a later date reverse its reversal.

- (3) Within three (3) business days after making the decision to reverse its adverse determination or final adverse determination, the health carrier shall notify the aggrieved person and the external review organization in writing of its decision. The external review organization shall terminate the external review upon receipt of the notice from the health carrier sent pursuant to subdivision (I)(3).
- (k) In addition to the documents and information provided pursuant to subsections (g) and (h), the external review organization, to the extent that the information or documents are available and the external review organization considers them appropriate, shall consider the following in reaching a decision:
  - (1) The covered person's pertinent medical records;
  - (2) The attending health care professional's recommendation;
  - (3) The consulting reports from appropriate health care professionals and other documents submitted by the aggrieved person or the covered person's treating physician or health care professional;
  - (4) The terms of coverage under the covered person's health benefit plan with the health carrier to ensure that the external review organization's decision is not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier;
  - (5) Any applicable clinical review criteria developed and used by the health carrier:
  - (6) The most appropriate practice guidelines, which shall include applicable medical or scientific evidence based standards;
  - (7) Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including:
    - (A) The Agency for Healthcare Research and Quality;
    - (B) The National Institutes of Health;

- (C) The National Cancer Institute;
- (D) The National Academy of Sciences;
- (E) The Centers for Medicare & Medicaid Services;
- (F) The Federal Food and Drug Administration; and
- (G) Any national board recognized by the National Institutes of health for the purpose of evaluating the medical value of health care services; and
- (8) The opinion of the external review organization's clinical reviewer or reviewers after considering subdivisions (1) (7), to the extent the information or documents are available and the clinical reviewer or reviewers consider appropriate.
- (I) In reaching a decision, the external review organization is not bound by any decisions or conclusions reached during the health carrier's internal grievance process as set forth in this chapter. However, the external review organization shall be bound by the terms and conditions of the covered person's health benefit plan.
- (m) Within forty-five (45) days after the date of receipt of the request for an external review, the external review organization shall provide written notice of its decision to uphold or reverse the adverse determination or the final adverse determination to the health carrier.
- (n) Within one (1) business day after rendering the decision under subsection (m), the external review organization shall notify the health carrier. Within three (3) business days after receiving the decision from the external review organization, the health carrier shall notify the aggrieved person of the external review organization's decision to uphold or reverse the adverse determination or final adverse determination. If the decision involved health care provider compensation, the health carrier shall make appropriate payment to the

health care provider within ten (10) business days of the receipt of a notice of the external review organization's decision.

- (o) The external review organization shall include in the notice sent pursuant to subsection (m):
  - A general description of the reason for the request for external review;
  - (2) The date that the external review organization received the assignment from the health carrier to conduct the external review;
    - (3) The date that the external review was conducted;
    - (4) The date of the external review organization's decision;
  - (5) The principal reason or reasons for the external review organization's decision, including any applicable, medical or scientific evidence based standards used as a basis for its decision:
  - (6) The rationale for the external review organization's decision; and
  - (7) References to the evidence or documentation, including the medical or scientific evidence based standards, considered in reaching the external review organization's decision.
- (p) Upon receipt of a notice of a decision pursuant to subsection (m) reversing the adverse determination or final adverse determination, the health carrier shall immediately approve the coverage that was the subject of the adverse determination or final adverse determination. If the decision involved health care provider compensation, the health carrier shall make appropriate payment to the health care provider within ten (10) business days of the receipt of a notice of the external review organization's decision.
- (q) The health carrier, regardless of URAC accreditation, shall have a contract with at least two (2) or more external review entities and may give the aggrieved person the opportunity to select, from among the external review

organizations that the health carrier has contracts with, the external review organization to conduct the review.

# SECTION 18.

- (a) Except as provided in subsection (f), an aggrieved person may make a request for an expedited external review with the health carrier at the time the aggrieved person receives:
  - (1) An adverse determination if:
  - (A) The adverse determination involves a medical condition of the covered person for which the time-frame for completion of an expedited internal review of a grievance involving an adverse determination set forth in SECTION 10 would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function; and
  - (B) The aggrieved person has filed a request for an expedited review of a grievance involving an adverse determination as set forth in SECTION 10; or
  - (2) A final adverse determination:
  - (A) If the covered person has a medical condition where the time-frame for completion of a standard external review pursuant to SECTION 17 would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function; or
  - (B) If the final adverse determination concerns an admission, availability of care, continued stay or health care service for which the covered person received emergency services, but has not been discharged from a facility.

- (1) Immediately upon receipt of the request, the health carrier shall determine whether the request meets the reviewability requirements set forth in SECTION 17. The health carrier shall immediately notify the aggrieved person of its eligibility determination regarding the availability of external review.
- (2) The notice of initial determination shall include a statement informing the aggrieved person that a health carrier's initial determination that an external review request is ineligible for review and that the aggrieved person, may file a complaint with the commissioner.
  - (A) The commissioner may determine that a request is eligible for external review notwithstanding a health carrier's initial determination that the request is ineligible and that it be referred to external review.
  - (B) In making a determination under (A), the commissioner's decision shall be made in accordance with the terms of the covered person's health benefit plan and shall be subject to all applicable provisions of this chapter.
- (c) Upon making a determination that a request is eligible for expedited external review the health carrier shall immediately notify the aggrieved person in writing that the request is eligible for external review.
- (d) At the same time, the health carrier shall immediately notify the external review organization and provide or transmit all necessary documents and information considered when making the adverse determination or final adverse determination electronically or by telephone, facsimile or any other expeditious method available.
- (e) In addition to the documents and information provided or transmitted pursuant to subsection (d), the external review organization, to the extent that the

information or documents are available and the external review organization considers them appropriate, shall consider the following in reaching a decision:

- (1) The covered person's pertinent medical records;
- (2) The attending health care professional's recommendation;
- (3) Consulting reports from appropriate health care professionals and other documents submitted by the health carrier or the aggrieved person;
- (4) The terms of coverage under the covered person's health benefit plan with the health carrier to ensure that the external review organization's decision is not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier;
- (5) The most appropriate practice guidelines, which shall include medical or scientific evidence based standards;
- (6) Applicable clinical review criteria developed and used by the health carrier in making adverse determinations; and
- (7) Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including:
  - (A) The Federal Agency for Healthcare Research and Quality;
    - (B) The National Institutes of Health;
    - (C) The National Cancer Institute;
    - (D) The National Academy of Sciences;
    - (E) The Centers for Medicare & Medicaid Services:
    - (F) The Federal Food and Drug Administration; and
  - (G) Any national board recognized by the National Institutes of health for the purpose of evaluating the medical value of health care services; and

- (8) The opinion of the external review organization's clinical reviewer or reviewers after considering subdivisions (e)(1) (7) to the extent that the information and documents are available and the clinical reviewer or reviewers consider appropriate.
- (f) As expeditiously as the covered person's medical condition or circumstances requires, but in no event more than seventy-two (72) hours after the date of receipt of the request for an expedited external review that meets the reviewability requirements, the external review organization shall make a decision to uphold or reverse the adverse determination or final adverse determination; and
  - (1) Notify the health carrier of the decision and the health carrier must immediately notify the aggrieved person of the external review organization's decision. The aggrieved person must receive the decision of the expedited external review within seventy-two (72) hours after the date of receipt of the request for expedited external review.

(2)

- (A) If the notice provided pursuant to subsection (f) was not in writing, within forty-eight (48) hours after the date of providing such notice, the external review organization shall provide written confirmation of the decision to the health carrier; and include the information set forth in SECTION 18.
- (B) The health carrier shall immediately notify the aggrieved person of the external review organization's decision and include the information set forth in SECTION 18.
- (C) Upon receipt of notice of the decision rendered pursuant to subdivision (f)(1) reversing the adverse determination or final adverse determination, the health carrier shall immediately

- approve the coverage that was the subject of the adverse determination or the final adverse determination.
- (g) An expedited external review shall not be provided for retrospective adverse determinations or final adverse determinations.SECTION 19.
- (a) Within six (6) months after the date of receipt of a notice of an adverse determination or final adverse determination that involves a denial of coverage based on a determination that the health care service or treatment recommended or requested is investigational an aggrieved person may file a request for external review with the health carrier.
- (b) Within ten (10) business days following the date of receipt of the copy of the external review request, the health carrier shall conduct and complete a preliminary review of the request to determine whether:
  - (1) The individual is or was a covered person in the health benefit plan at the time that the health care service or treatment was recommended or requested or, in the case of a retrospective review, was a covered person in the health benefit plan at the time that the health care service or treatment was provided;
  - (2) The recommended or requested health care service or treatment that is the subject of the adverse determination or final adverse determination:
    - (A) Is a covered benefit under the covered person's health benefit plan except for the health carrier's determination that the service or treatment is experimental or investigational for a particular medical condition; and
    - (B) Is not explicitly listed as an excluded benefit under the covered person's health benefit plan with the health carrier;

- (3) The covered person's treating physician has certified that one(1) of the following situations is applicable:
  - (A) Standard health care services or treatments have not been effective in improving the condition of the covered person;
  - (B) Standard health care services or treatments are not medically appropriate for the covered person; or
  - (C) There is no available standard health care service or treatment covered by the health carrier that is more beneficial than the recommended or requested health care service; or
  - (4) The covered person's treating physician:
  - (A) Has recommended a health care service or treatment that the physician certifies, in writing, is likely to be more beneficial to the covered person, in the physician's opinion, than any available standard health care services or treatments; or
  - (B) Who is a licensed, board certified or board eligible physician qualified to practice in the area of medicine appropriate to treat the covered person's condition, has certified in writing that scientifically valid studies using accepted protocols demonstrate that the health care service or treatment requested by the covered person that is the subject of the adverse determination or final adverse determination is likely to be more beneficial to the covered person than any available standard health care services or treatments;
- (5) The aggrieved person has exhausted the health carrier's internal grievance process as set forth in this chapter unless the aggrieved person is not required to exhaust the health carrier's internal grievance process pursuant to SECTION 16; and

- (6) The aggrieved person has provided all the information and forms that are necessary to process an external review, including the release form provided under SECTION 14.
- (c) Within three (3) business days after completion of the preliminary review, the health carrier shall notify the aggrieved person in writing whether:
  - (1) The request is complete; and
  - (2) The request is eligible for external review.
  - (d) If the request set out in subsection (a):
  - (1) Is not complete, the health carrier shall notify the aggrieved person, in writing, and include in the notice what information or materials are needed to make the request complete; or
  - (2) Is not eligible for external review, the health carrier shall notify the aggrieved person in writing and include in the notice the reasons for its ineligibility.
- (e) The notice of initial determination shall include a statement informing the aggrieved person that a health carrier's initial determination that the external review request is ineligible for review may be appealed to the commissioner.

(f)

- (1) The commissioner may determine that a request is eligible for external review under this chapter notwithstanding a health carrier's initial determination that the request is ineligible and require that it be referred for external review.
- (2) In making a determination under this subsection, the commissioner's decision shall be made in accordance with the terms of the covered person's health benefit plan and shall be subject to all applicable provisions of this chapter.

(g)

- (1) Whenever the health carrier or commissioner determines that a request is eligible for external review following the preliminary review conducted pursuant to subdivision (c)(2), within three (3) business days after the determination by the health carrier or within three (3) business days after the date of receipt of the determination by the commissioner, the health carrier shall notify the aggrieved person in writing of the request's eligibility and acceptance for external review.
- (2) The health carrier shall include in the notice provided to the aggrieved person, a statement that additional information may be submitted in writing to the health carrier, within six (6) business days following the date of receipt of the notice provided pursuant to this subsection (g), that the external review organization shall consider when conducting the external review. The health carrier is not required to, but may, accept and forward to the external review organization for consideration such additional information submitted by the aggrieved person after six (6) business days.
- (3) Within one (1) business day after the receipt of the notice of the request to conduct external review, the external review organization shall:
  - (A) Select one (1) or more clinical reviewers, as it determines is appropriate, pursuant to subsection (o) to conduct the external review; and
  - (B) Based on the opinion of the clinical reviewer, or opinions if more than one (1) clinical reviewer has been selected to conduct the external review, make a decision to uphold or reverse the adverse determination or final adverse determination.
- (4) In selecting clinical reviewers pursuant to subdivision (g)(3), the external review organization shall select physicians or other health

care professionals who meet the minimum qualifications described in SECTION 22 and, through clinical experience in the past three (3) years, are experts in the treatment of the covered person's condition and knowledgeable about the recommended or requested health care service or treatment.

- (5) Neither the aggrieved person nor the health carrier shall choose or control the choice of the physicians or other health care professionals selected to conduct the external review.
- (6) In accordance with subsection (h), each clinical reviewer shall provide a written opinion to the external review organization on whether the recommended or requested health care service or treatment should be covered.
- (7) In reaching an opinion, clinical reviewers are not bound by any decisions or conclusions reached during the health carrier's internal grievance process.

(h)

- (1) Within six (6) business days after the date of receipt of the notice provided pursuant to subsections (c) or (f), the health carrier shall provide to the external review organization, any documents and information considered in making the adverse determination or the final adverse determination.
- (2) Failure by the health carrier to provide the documents and information within the time specified in subsection (h) shall not delay the conduct of the external review.
- (3) If the health carrier fails to provide the documents and information within the time specified in subsection (h), the external review organization may terminate the external review and make a decision to reverse the adverse determination or final adverse determination.

- (4) The external review organization shall notify the health carrier within one (1) business day of its decision to reverse the adverse determination or final adverse determination pursuant to subdivision
  (h)(3). The health carrier shall notify the aggrieved person within three (3) business days of the external review organization's decision.
- (i) Each clinical reviewer selected pursuant to subdivision (g)(3) shall review all of the information and documents received pursuant to subdivision (g)(2) and any other information submitted in writing by the aggrieved person.

(j)

- (1) Upon receipt of the information required to be forwarded pursuant to subdivision (g)(2), the health carrier may reconsider its adverse determination or final adverse determination that is the subject of the external review.
- (2) Reconsideration by the health carrier of its adverse determination or final adverse determination shall not delay or terminate the external review.
- (3) The external review may terminate only if the health carrier decides, upon completion of its reconsideration, to reverse its adverse determination or final adverse determination and provide coverage or payment for the recommended or requested health care service or treatment that is the subject of the adverse determination or final adverse determination.
- (4) Within three (3) business days after making the decision to reverse its adverse determination or final adverse determination, the health carrier shall notify the aggrieved person of its decision in writing.
- (5) The external review organization shall terminate the external review upon receipt of the notice from the health carrier sent pursuant to subdivision (j)(4).

- (k) Within twenty (20) days after being selected in accordance with subdivision (g)(3) to conduct the external review, each clinical reviewer shall provide an opinion to the external review organization on whether the recommended or requested health care service or treatment should be covered. Each clinical reviewer's opinion shall be in writing and include the following information:
  - (1) A description of the covered person's medical condition;
  - (2) A description of the indicators relevant to determining whether there is sufficient evidence to demonstrate that the recommended or requested health care service or treatment is more likely than not to be beneficial to the covered person than any available standard health care services or treatments and the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those available standard health care services or treatments;
  - (3) A description and analysis of any medical or scientific evidence, as that term is defined by this chapter; and
  - (4) Information on whether the reviewer's rationale for the opinion is based on subdivision (I)(5).
- (I) In addition to the documents and information provided pursuant to subsection (g), each clinical reviewer, to the extent that the information or documents are available and the reviewer considers appropriate, shall consider the following in reaching an opinion pursuant to subsection (k):
  - (1) The covered person's pertinent medical records:
  - (2) The attending physician or health care professional's recommendation:

- (3) Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, aggrieved person, or the covered person's treating physician or health care professional;
- (4) The terms of coverage under the covered person's health benefit plan with the health carrier to ensure that, but for the health carrier's determination that the recommended or requested health care service or treatment that is the subject of the opinion is experimental or investigational, the reviewer's opinion is not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier; and

# (5) Whether:

- (A) The recommended or requested health care service or treatment has been approved by the Federal Food and Drug Administration, if applicable, for the condition; or
- (B) Medical or scientific evidence based standards that demonstrate that the expected benefits of the recommended or requested health care service or treatment is more likely than not to be beneficial to the covered person than any available standard health care service or treatment and the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments.

(m)

(1) Within twenty (20) days after the date it receives the opinion of each clinical reviewer, the external review organization, shall make a decision and provide written notice of the decision to the health carrier.

The health carrier shall notify the aggrieved person, within three (3) business days of the external review organization decision.

- (2) If a majority of the clinical reviewers recommend that the recommended or requested health care service or treatment should be covered, the external review organization shall render a decision to reverse the health carrier's adverse determination or final adverse determination.
- (3) If a majority of the clinical reviewers recommend that the recommended or requested health care service or treatment should not be covered, the external review organization shall render a decision to uphold the health carrier's adverse determination or final adverse determination.
- (4) If the clinical reviewers are evenly split as to whether the recommended or requested health care service or treatment should be covered, then the external review organization shall obtain the opinion of an additional clinical reviewer in order for the external review organization to render a decision based on the opinions of a majority of the clinical reviewers; provided that:
  - (A) The additional clinical reviewer selected under this subdivision (m) shall use the same information to reach an opinion as the clinical reviewers who have already submitted their opinions pursuant to subsection (i).
  - (B) The selection of the additional clinical reviewer under this subdivision (m) shall not extend the time within which the external review organization is required to render a decision based on the opinions of the clinical reviewers selected under subsection (g).
- (5) The external review organization shall include in the notice provided pursuant to this subsection (m):

- (A) A general description of the reason for the request for external review;
- (B) The written opinion of each clinical reviewer, including the recommendation of each clinical reviewer as to whether the recommended or requested health care service or treatment should be covered and the rationale for the clinical reviewer's recommendation;
- (C) The date that the external review organization was notified by the health carrier to conduct the external review;
  - (D) The date that the external review was conducted;
  - (E) The date of external review organization's decision;
- (F) The principal reason or reasons for external review organization's decision; and
- (G) The rationale for external review organization's decision.
- (6) Upon receipt of a notice of a decision reversing the adverse determination or final adverse determination, the health carrier shall immediately approve coverage of the recommended or requested health care service or treatment that was the subject of the adverse determination or final adverse determination. If the decision involved health care provider compensation, the health carrier shall make appropriate payment to the health care provider within ten (10) business days of the receipt of a notice of the decision from the external review organization.

(n)

(1) Within six (6) months after the date of a notice of an adverse determination that involves a denial of coverage based upon the determination that the health care service or treatment recommended or

requested is experimental or investigational, an aggrieved person may file a request for an expedited external review of the adverse determination. The covered person's treating physician must certify, in writing, that the recommended or requested health care service or treatment that is the subject of the request would be significantly less effective if not promptly initiated.

- (2) Upon notice of the request for expedited external review, the health carrier shall immediately determine whether the request meets the reviewability requirements of subsection (b). The health carrier shall immediately notify the aggrieved person of its eligibility determination.
- (3) The notice of initial determination shall include a statement informing the aggrieved person that a health carrier's initial determination that the request for external review is ineligible for review and may be appealed to the commissioner; provided that:
  - (A) The commissioner may determine that a request is eligible for external review notwithstanding a health carrier's initial determination that the request is ineligible and that it be referred to external review; and
  - (B) In making a determination under subdivision (n)(3)(A), the commissioner's decision shall be made in accordance with the terms of the covered person's health benefit plan and shall be subject to all applicable provisions of this chapter.
- (4) Upon making a determination that a request is eligible for expedited external review, the health carrier shall immediately notify the aggrieved person in writing the request is eligible for external review.
- (5) At the same time, the health carrier shall immediately notify the external review organization and provide or transmit all necessary documents and information considered when making the adverse

determination or final adverse determination electronically or by telephone, facsimile or any other expeditious method available.

- (6) Within one (1) business day after the receipt of the notice to conduct an expedited external review, the external review organization shall:
  - (A) Select one (1) or more clinical reviewers, as it deems appropriate to conduct the expedited external review;
  - (B) Based on the decision of the clinical reviewer or reviewers render a decision to uphold or reverse the decision of the adverse determination;
  - (C) Require each clinical reviewer to provide an opinion, orally or in writing, to the external review organization as expeditiously as the covered person's medical condition or circumstances requires, but in no event more than five (5) days after being selected; and
  - (D) If the opinion was not in writing, within forty-eight (48) hours following the date that the opinion was provided, require the clinical reviewer to provide written confirmation of the opinion to the external review organization and include the information required in subsection (k) and (l).
- (7) Upon receipt of a notice of a decision reversing the adverse determination, the health carrier shall immediately approve the coverage of the recommended or requested health care service or treatment that was the subject of the adverse determination.
- (o) The health carrier, regardless of URAC accreditation, shall have a contract with at least two (2) or more external review entities and may give the aggrieved person the opportunity to select, from among the external review

organizations that the health carrier has contracts with, the external review organization to conduct the review.

#### SECTION 20.

- (a) An external review decision is binding on the health carrier except to the extent that the health carrier has other remedies available under applicable federal or state law.
- (b) An external review decision is binding on the covered person except to the extent that the covered person has other remedies available under applicable federal or state law.
- (c) An external review decision is binding on the health care provider except to the extent that the health care provider has other remedies available under applicable federal or state law.
- (d) A aggrieved person, may not file a subsequent request for external review involving the same adverse determination or final adverse determination for which the covered person has already received an external review decision pursuant to this chapter.

# SECTION 21.

- (a) The commissioner shall approve external review organizations eligible to conduct external reviews under this chapter.
- (b) In order to be eligible for approval by the commissioner to conduct external reviews under this chapter, an external review organization:
  - (1) Except as otherwise provided in this section, shall be accredited by a nationally recognized private accrediting entity that the commissioner has determined has external review organization accreditation standards that are equivalent to or exceed the minimum qualifications for external review organizations established under SECTION 22; and

- (2) Shall submit an application for approval in accordance with subsection (d).
- (c) The commissioner shall develop an application form for initially approving and for reapproving external review organizations to conduct external reviews.
- (d) Any external review organization wishing to be approved to conduct external reviews under this chapter shall submit the application form and include with the form all documentation and information necessary for the commissioner to determine if the external review organization satisfies the minimum qualifications established under SECTION 22.
- (e) Subject to subsection (b), an external review organization is eligible for approval under this section only if it is accredited by a nationally recognized private accrediting entity that the commissioner has determined has external review organization accreditation standards that are equivalent to or exceed the minimum qualifications for external review organizations under SECTION 22.
- (f) The commissioner may approve external review organizations that are not accredited by a nationally recognized private accrediting entity if there are no acceptable nationally recognized private accrediting entities providing external review organization accreditation.
- (g) The commissioner may charge an application fee that external review organizations shall submit to the commissioner with an application for approval and reapproval.
- (h) An approval is effective for two (2) years, unless the commissioner determines before its expiration that the external review organization is not satisfying the minimum qualifications established under SECTION 22. Whenever the commissioner determines that an external review organization has lost its accreditation or no longer satisfies the minimum requirements established under SECTION 22, the commissioner shall terminate the approval of the external

review organization and remove the external review organization from the list of external review organizations approved to conduct external reviews under this chapter that is maintained by the commissioner pursuant to subsection (i).

- (i) The commissioner shall maintain and periodically update a list of approved external review organizations.
- (j) The commissioner may promulgate rules and regulations to carry out the provisions of this section.

## SECTION 22.

- (a) To be approved under SECTION 21 to conduct external reviews, an external review organization shall have and maintain written policies and procedures that govern all aspects of both the standard external review process and the expedited external review process set forth in this chapter that include, at a minimum:
  - (1) A quality assurance mechanism in place that:
  - (A) Ensures that external reviews are conducted within the specified time frames and required notices are provided in a timely manner;
  - (B) Ensures the selection of qualified and impartial clinical reviewers to conduct external reviews on behalf of the external review organization; suitable matching of reviewers to specific cases; and that the independent review organization employs or contracts with an adequate number of clinical reviewers to meet this objective;
  - (C) Ensures the confidentiality of medical and treatment records and clinical review criteria; and
  - (D) Ensures that any person employed by or under contract with the external review organization adheres to the requirements of this chapter;

- (2) A toll-free telephone service to receive information on a twenty-four (24) hour a day, seven (7) day a week basis related to external reviews that is capable of accepting, recording or providing appropriate instruction to incoming telephone callers during hours outside of normal business hours; and
- (3) Agree to maintain and provide to the commissioner the information set out in SECTION 26.
- (b) All clinical reviewers aggrieved by an external review organization to conduct external reviews shall be physicians or other appropriate health care providers who meet the following minimum qualifications:
  - (1) Be an expert in the treatment of the covered person's medical condition that is the subject of the external review;
  - (2) Be knowledgeable about the recommended health care service or treatment through recent or current actual clinical experience treating patients with the same or similar medical condition of the covered person;
  - (3) Hold a non-restricted license in a state of the United States and, for physicians, a current certification by a recognized American medical specialty board in the area or areas appropriate to the subject of the external review; and
  - (4) Have no history of disciplinary actions or sanctions, including loss of staff privileges or participation restrictions, that have been taken or are pending by any hospital, governmental agency or unit, or regulatory body that raise a substantial question as to the clinical reviewer's physical, mental or professional competence or moral character.
- (c) In addition to the requirements set forth in subsection (a), an external review organization may not own or control, be a subsidiary of or in any way be owned or controlled by, or exercise control with a health benefit plan, a national,

state or local trade association of health benefit plans, or a national, state or local trade association of health care providers.

- (d) In addition to the requirements set forth in subsections (a), (b) and (c), to be approved pursuant to SECTION 23 to conduct an external review of a specified case, neither the external review organization selected to conduct the external review nor any clinical reviewer assigned by the external organization to conduct the external review may have a material professional, familial or financial conflict of interest with any of the following:
  - (1) The health carrier that is the subject of the external review:
  - (2) The covered person whose treatment is the subject of the external review or the covered person's authorized representative;
  - (3) Any officer, director or management employee of the health carrier that is the subject of the external review;
  - (4) The health care provider, the health care provider's medical group or independent practice association recommending the health care service or treatment that is the subject of the external review;
  - (5) The facility at which the recommended health care service or treatment would be provided; or
  - (6) The developer or manufacturer of the principal drug, device, procedure or other therapy being recommended for the covered person whose treatment is the subject of the external review.
- (e) In determining whether an external review organization or a clinical reviewer of the external review organization has a material professional, familial or financial conflict of interest for purposes of subsection (d), the commissioner shall take into consideration situations where the external review organization conducting an external review of a specified case or a clinical reviewer to be assigned by the external review organization to conduct an external review of a specified case may have an apparent professional, familial or financial

relationship or connection with a person described in subsection (d), but that the characteristics of that relationship or connection are such that they are not a material professional, familial or financial conflict of interest that results in the disapproval of the independent review organization or the clinical reviewer from conducting the external review.

- (f) An external review organization that is accredited by a nationally recognized private accrediting entity that has external review accreditation standards that the commissioner has determined are equivalent to or exceed the minimum qualifications of this section shall be presumed in compliance with this section to be eligible for approval under SECTION 23.
- (g) The commissioner shall initially review and periodically review the external review organization accreditation standards of a nationally recognized private accrediting entity to determine whether the entity's standards are, and continue to be, equivalent to or exceed the minimum qualifications established under this section. The commissioner may accept a review conducted by the NAIC for the purpose of the determination under this subsection (g).
- (h) Upon request, a nationally recognized private accrediting entity shall make its current external review organization accreditation standards available to the commissioner or the NAIC in order for the commissioner to determine if the entity's standards are equivalent to or exceed the minimum qualifications established under this section. The commissioner may exclude any private accrediting entity that is not reviewed by the NAIC.
- (i) An external review organization shall be unbiased. An external review organization shall establish and maintain written procedures to ensure that it is and remains unbiased in addition to any other procedures required under this section.

SECTION 23. No external review organization or clinical reviewer working on behalf of an external review organization or an employee, agent or contractor of an

external review organization shall be liable in damages to any person for any opinions rendered or acts or omissions performed within the scope of the organization's or person's duties under the law during or upon completion of an external review conducted pursuant to this chapter, unless the opinion was rendered or act or omission performed in bad faith or involved gross negligence.

## SECTION 24.

- (a) An external review organization conducting an external review pursuant to this chapter shall maintain written records in the aggregate by state and by health carrier on all requests for external review for which it conducted an external review during a calendar year and, upon request, submit a report to the commissioner, as required under subdivision (a)(2).
  - (1) Each external review organization required to maintain written records on all requests for external review for which it conducted an external review shall submit to the commissioner, upon request, a report in the format specified by the commissioner.
  - (2) The report shall include in the aggregate by state, and for each health carrier:
    - (A) The total number of requests for external review;
    - (B) The number of requests for external review resolved and, of those resolved, the number resolved upholding the adverse determination or final adverse determination and the number resolved reversing the adverse determination or final adverse determination;
      - (C) The average length of time for resolution;
    - (D) A summary of the types of coverages or cases for which an external review was sought, as provided in the format required by the commissioner;

- (E) The number of external reviews pursuant to SECTION 17 that were terminated as the result of a reversal by the health carrier of its adverse determination or final adverse determination after the receipt of additional information from the aggrieved person; and
- (F) Any other information that the commissioner may request or require.
- (3) The external review organization shall retain the written records required pursuant to this subsection (a) for at least three (3) years.
- (b) Each health carrier shall maintain written records in the aggregate, by state and for each type of health benefit plan offered by the health carrier on all requests for external review that the health carrier receives notice of from the commissioner pursuant to this chapter.
  - (1) Each health carrier required to maintain written records on all requests for external review pursuant to this subsection (b) shall submit to the commissioner, upon request, a report in the format specified by the commissioner.
  - (2) The report shall include in the aggregate, by state, and by type of health benefit plan:
    - (A) The total number of requests for external review;
    - (B) From the total number of requests for external review reported under subdivision (b)(2)(A), the number of requests determined eligible for a full external review; and
    - (C) Any other information that the commissioner may request or require.
  - (3) The health carrier shall retain the written records required pursuant to this subsection (b) for at least three (3) years.

SECTION 25. The health carrier against which a request for a standard external review or an expedited external review is filed shall pay the cost of the external review organization for conducting the external review.

#### SECTION 26.

- (a) Each health carrier shall include a description of the external review procedures in or attached to the membership booklet, provider manual, and health carrier's web site. The health carrier may include a description of the external review procedures in the policy, certificate, outline of coverage, or other evidence of coverage provided to covered persons and providers.
- (b) The disclosure required by subsection (a) shall be in a format prescribed by the commissioner.
- (c) The description required under subsection (a) shall include a statement that informs the aggrieved person of the aggrieved person's right to file a request for an external review of an adverse determination or final adverse determination with the carrier. The statement shall include the telephone number and address of the commissioner.
- (d) In addition to subsection (b), the statement shall inform the covered person that, when filing a request for an external review, the covered person will be required to authorize the release of any medical records of the covered person that may be required to be reviewed for the purpose of reaching a decision on the external review.

SECTION 27. Tennessee Code Annotated, Section 56-32-110, is amended by deleting the section in its entirety.

SECTION 28. Tennessee Code Annotated, Section 56-32-127, is amended by deleting the section in its entirety.

SECTION 29. Tennessee Code Annotated, Section 56-32-103(b)(11), is amended by deleting the subdivision in its entirety and by substituting instead:

(b)

(11) A description of the complaint procedure to be utilized pursuant to the Tennessee Health Carrier Grievance and External Review Procedure Act, compiled in title 56; and

SECTION 30. If any provision of this act, or the application of any provision to any person or circumstance shall be held invalid, the remainder of the act, and the application of the provision to persons or circumstances other than those to which it is held invalid, shall not be affected.

SECTION 31. For purposes of promulgating rules and regulations, this act shall take effect upon becoming a law, the public welfare requiring it, for all other purposes, this act shall take effect January 1, 2011.